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| APPLICATION NO.                       | FILING DATE                      | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
|---------------------------------------|----------------------------------|----------------------|-------------------------|------------------|--|
| 10/743,125                            | 12/22/2003                       | Peter M. Bonutti     | 2500DV2CN2DV3CN6        | 7494             |  |
| 7590 12/05/2006                       |                                  |                      | EXAMINER                |                  |  |
| Kimberly V. I                         | Perry, Esq.                      | KASZTEJNA, MA        | KASZTEJNA, MATTHEW JOHN |                  |  |
| U.S. Surgical                         | Coor II and the coor Coorses I D | ART UNIT             | PAPER NUMBER            |                  |  |
| 150 Glover Ave                        | Yco Healthcare Group, LP         | 3739                 |                         |                  |  |
| Norwalk, CT 06856                     |                                  |                      | 3137                    |                  |  |
| · · · · · · · · · · · · · · · · · · · |                                  |                      | DATE MAILED: 12/05/2006 |                  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| · · · · · · · · · · · · · · · · · · ·   |  | Application No.  | Applicant(s)   |                   |  |  |  |
|---|--|--|--|-------------------|--|--|--|
| Office Action Summary   |  | 10/743,125   | BONUTTI, PETE  | BONUTTI, PETER M. |  |  |  |
|   |  | Examiner   | Art Unit   |                   |  |  |  |
|   |  | Matthew J. Kasztejna   | 3739   |                   |  |  |  |
| Period fo   | The MAILING DATE of this communication ap<br>or Reply  | pears on the cover sheet with  | the correspondence a   | ddress            |  |  |  |
| WHIC<br>- Exte<br>after<br>- If NC<br>- Failt<br>Any  | ORTENED STATUTORY PERIOD FOR REPI<br>CHEVER IS LONGER, FROM THE MAILING I<br>nsions of time may be available under the provisions of 37 CFR 1<br>SIX (6) MONTHS from the mailing date of this communication.<br>o period for reply is specified above, the maximum statutory period<br>are to reply within the set or extended period for reply will, by statute<br>reply received by the Office later than three months after the mailined patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUNICA<br>136(a). In no event, however, may a repl<br>will apply and will expire SIX (6) MONTH<br>te, cause the application to become ABAN | ATION.  ly be timely filed  IS from the mailing date of this of the second seco |                   |  |  |  |
| Status  |  |  |  |                   |  |  |  |
| 1)  🏻   | Responsive to communication(s) filed on <u>08</u> .  | Sentember 2006   |  |                   |  |  |  |
| 2a)□  |  | s action is non-final.   |  |                   |  |  |  |
| 3)  |  |  |  |                   |  |  |  |
| ٠,۵   | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |  |  |                   |  |  |  |
| Disposit  | ion of Claims  |  | ,<br>,   |                   |  |  |  |
| 4)⊠   | Claim(s) 11-19 is/are pending in the application   | on.  |  |                   |  |  |  |
| 7,43  | 4a) Of the above claim(s) is/are withdrawn from consideration.   |  |  |                   |  |  |  |
| 5) 🗌  | 5) Claim(s) is/are allowed.  |  |  |                   |  |  |  |
| ·   | 6)⊠ Claim(s) <u>11-19</u> is/are rejected.   |  |  |                   |  |  |  |
| 7)  | Claim(s) is/are objected to.   | •  |  |                   |  |  |  |
| • —   | Claim(s) are subject to restriction and/   | or election requirement.   |  |                   |  |  |  |
|   |  |  |  |                   |  |  |  |
| Application Papers  |  |  |  |                   |  |  |  |
| •   | The specification is objected to by the Examin   |  | shipping to buthe Fron   | i                 |  |  |  |
| 10) ☐ The drawing(s) filed on 22 December 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.                             |  |  |  |                   |  |  |  |
|   | Applicant may not request that any objection to the  | ***  | •  | SED 4 4047/10     |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).              |  |  |  |                   |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.                          |  |  |  |                   |  |  |  |
| Priority (  | under 35 U.S.C. § 119  |  |  |                   |  |  |  |
| 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) ☐ All b) ☐ Some * c) ☐ None of: |  |  |  |                   |  |  |  |
|   | 1. Certified copies of the priority documents have been received.  |  |  |                   |  |  |  |
|   | 2. Certified copies of the priority documents have been received in Application No   |  |  |                   |  |  |  |
|   | 3. Copies of the certified copies of the priority documents have been received in this National Stage  |  |  |                   |  |  |  |
|   | application from the International Bureau (PCT Rule 17.2(a)).  |  |  |                   |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.  |  |  |  |                   |  |  |  |
|   |  |  |  |                   |  |  |  |
| Attachmen   | t(s) .   |  |  |                   |  |  |  |
|   | e of References Cited (PTO-892)  |  | nmary (PTO-413)  |                   |  |  |  |
|   | e of Draftsperson's Patent Drawing Review (PTO-948)  |  | No(s)/Mail Date<br>of Informal Patent Application  |                   |  |  |  |
| 3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application  Other:           |  |  |  |                   |  |  |  |
|   |  |  |  |                   |  |  |  |

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#### **DETAILED ACTION**

### Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 8, 2006 has been entered.

#### Notice of Amendment

In response to the amendment filed on September 8, 2006, amended claims 11 and 18 are acknowledged. The current rejections of the claims under Solano et al. are withdrawn. The following new and reiterated grounds of rejection are set forth:

#### Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 11 of copending Application No. 10/729,634. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 of the instant application is broader than claims 1 and 9 of copending Application No. 10/729,634. Claims 1 and 11 of copending application No. 10/729,634 recite a retractor comprised of a shaft, inflatable bladder disposed at an end of the shaft where the bladder has an inflatable shape selected from the group consisting of circular, oval, eccentric, oblong, conical, wedge-shaped, V-shaped and multiple lobes, along with other features. Claim 11 of the instant application recites a retractor comprised of a shaft and an inflatable bladder that is eccentric or eccentrically mounted on the shaft. Furthermore, claims 13-17 and 19 of the instant invention are identical to claims 4-8 and 15 of copending Application No. 10/729,634, respectively.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of copending Application No. 10/743,192. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 of the instant application is broader than claims 1 and 7 of copending Application No. 10/743,192.

The combination of claims 1 and 7 disclose a similar retractor of the instant invention differing only in the shape of the inflatable bladder. Furthermore, claims 13-17 and 19 of the instant invention are identical to claims 2-6 and 9 of copending Application No. 10/743,192, respectively.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-21 of copending Application No. 10/729,768 (Note: Claims 15-21 refer to the most recent claim amendment on file in Application No. 10/729,768 - filed July 1, 2005). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 of the instant application is broader than claim 1 and 21 of copending Application No. 10/729,768. Claim 1 of copending Application No. 10/729,768 recites an apparatus comprised of a shaft and an inflatable bladder wherein the inflatable bladder has a shape selected from the group consisting of: eccentric, conical and wedge-shaped, along with other features. Claims 13-17 are identical to claims 16-20 of copending Application No. 10/729,768, respectively.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11-17 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,295,464 to Shihata.

In regards to claims 11-15 and 17-18, Shihata discloses an apparatus comprising: a shaft 101; an inflatable bladder 107 which is eccentrically mounted on the shaft; and a cannula 102 having a passage which receives the shaft to deploy the bladder at a target site in tissue and wherein the inflatable bladder is shaped so that it expands into an eccentric shape when inflated by fluid pressure introduced (see Fig. 2).

In regards to claim 16, Shihata discloses an apparatus, wherein the shaft is rigid (see Col. 5, Lines 45-60 and Col. 7, Lines 30-36).

In regards to claim 17, Shihata discloses an apparatus, wherein the shaft is flexible (see Col. 5, Lines 45-60 and Col. 7, Lines 30-36).

Claims 11-19 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,071,406 to Jang.

In regards to claims 11-19, Shihata discloses an apparatus comprising: a shaft; an inflatable bladder which is eccentrically mounted on the shaft; and a plurality of inflatable bladders positioned on the shaft and wherein the plurality of inflatable balloons are separately inflatable (see Figs. 2-19 and Cols. 4-7).

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### Response to Arguments

Applicant's arguments with respect to claims 11-19 have been considered but are most in view of the new ground(s) of rejection.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MJK MK

11/28/06

LÍNDA C. M. DVORAR SUPERVISORY PATENT EXAMINER

GROUP 3700